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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,936	11/07/2001	Olle Korsgren	KORSGREN=1	9165

1444 7590 06/02/2011

Browdy and Neimark, PLLC
1625 K Street, N.W.
Suite 1100
Washington, DC 20006

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/02/2011	PAPER

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RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex Parte OLLE KORSGREN *et al.*

Appeal 2009-015372
Application 09/890,936
Technology Center 1600

Oral Hearing Held: Thursday, January 13, 2011

Before ERIC B. GRIMES, MELANIE L. MCCOLLUM and JEFFREY N. FREDMAN, Administrative Patent Judges

ON BEHALF OF THE APPELLANT:

SHERIDAN NEIMARK, ESQ.
1625 K Street, N.W.
Washington, D.C. 20006
(202) 628-5197

The above-entitled matter came on for hearing on Thursday, January 13, 2011, commencing at 1:02 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Alexandria, Virginia, before Lori Beth Allen, Notary Public.

THE CLERK: 015372, Mr. Neimark.
JUDGE GRIMES: Good afternoon, Mr. Neimark.
MR. NEIMARK: Good afternoon. I'm Sheridan Neimark.
JUDGE GRIMES: Welcome.
As you probably know, you'll have 20 minutes to present your case, and you can settle in and get started whatever you're ready.
MR. NEIMARK: I hope it takes less than 20.
The present invention relates to a method as recited in Main Claim 4, for transplanting, in a patient suffering from diabetes, insulin-producing cells in the form of individually isolated islets treated with heparin, so that the heparin is surface-bound to the islets.
Now a key aspect in providing the bound, individually isolated islets, is pre-treating the islets, such as by pre-incubation in an aqueous solution with the heparin to achieve irreversible adsorption.
So the heparin is adsorbed onto the surfaces of the islets. In other words, the heparin is fixed to the individual islets, so that the heparin can function to protect the islets from incompatibility with the blood, and thus reduce clotting.
JUDGE FREDMAN: So my question to you is, we're dealing with two references that essentially use the concept of encapsulation with, very often it's algin.
Now we're using two references, Wagner and Soon-Shiong, who use the concept of encapsulation with things like alginates and other things.
And they do talk about including heparin in this thing that is encapsulating the islets.

So is it your position, then, that irreversible adsorption differs from encapsulation, because it's a direct attachment of the heparin to the islets, whereas encapsulation would be more of an indirect attachment, and therefore wouldn't be adsorbed to the islets, but would rather be adsorbed to the capsule around the islets?

MR. NEIMARK: Yeah. In fact, that's about nine-tenths of what I intended to present today. I think the evidence, the declarations, make it very clear. I don't know how much I should go into that.

Well, let me go ahead, and if I get boring, let me know.

I think that the Examiner has -- you know, we've made that argument over and over and over again, and she just refuses to accept it. And I don't know why. We've got the evidence to back it up. The treated islets in the present invention are absolutely not encapsulated. We've got the independent expert, Dr. James Shapiro, and he is a former president of the International Pancreas and Islet Transplantation Association from 2005 to 2007. And he confirms, basically confirms our position. He says on page 3 of his declaration, the terms "isolated islets" and "individually isolated islets" are quite distinct from islet encapsulation.

And on the same page later on, he says, and I quote -- well, what he says is that the individually isolated islets are "quite different from islet encapsulation."

And that pretty much confirms what appears in earlier declarations by the inventors, who are also highly qualified people. Of the four inventors, three of them are Ph.D. M.D.'s, and one is a Ph.D. And they say the same thing. We've got three of their declarations of record.

You know, I don't think there's any question. The Examiner doesn't have any evidence in support of her position, but I think we have very substantial evidence.

JUDGE GRIMES: Would the difference between adsorption to the cells and encapsulation, does absorption require a direct bond between the heparin and the cell itself?

MR. NEIMARK: Yes. As I understand it, the molecules of heparin are actually linked or bound to like kind of stick out from the surface of the islets.

JUDGE GRIMES: Whereas if it was encapsulated by some kind of gel that included heparin, there might be heparin surrounding the cell, but it wouldn't necessarily be bonded directly to the cell?

MR. NEIMARK: Yes. And not only that, but these shells, these capsules, are actually much bigger than the islets. And often these shells don't even touch the surface of the islets.

I think you'll see that if you look in the second declaration of the three of the four inventors. I talked about that a little bit here.

JUDGE FREDMAN: You talked about how this becomes a claim interpretation case. So what does it mean by "irreversible?"

Ultimately, it becomes a claim interpretation case of what does irreversible absorption mean? If it means direct contact, the Examiner clearly loses. If it means something else, the Examiner --

MR. NEIMARK: Well, it means it's a question of the heparin being bound to the cells.

JUDGE FREDMAN: Right.

MR. NEIMARK: And you know, that's what we claim, and the prior art doesn't have that. Of course, there's a lot -- there are other problems with the prior art.

For example, the Wagner publication. The only place it even mentions heparin is in one of the claims. I don't even think it's enabling for, you know, what you would do with the heparin.

It's certainly not enabling for anything that we do. You know, it's a real stretch.

I'm skipping ahead here. I think I mentioned that the capsules, and particularly Wagner mentions this -- he mentions that the capsules are a half of a millimeter to four millimeters, and two to three centimeters long.

And he's on another embodiment there, where they're half a millimeter. But they're much, much larger than the islets.

And in fact, it even says that in Wagner, that the capsules have volumes several times larger than that of the individual islets.

As I mentioned, the only place that heparin is even mentioned in Wagner is in Claim 7, which is dependent on Claim 6; and there's nothing really disclosed on what to do with the heparin.

I said that we don't think that Wagner even has an enabling disclosure with regard to the heparin; but even if it did, it would be in relation to encapsulating, not modifying individually isolated islets by irreversible adsorption, as claimed.

But more than the effect of Wagner not providing a disclosure, which would enable a person skilled in the art to do anything even approaching what Appellants claim, Wagner in any event doesn't disclose each and every element of the claimed invention, arranged or combined in the same way as in the Appellant's claim.

And I think that's pretty much accepted to be a requirement of Section 102.

The second rejection under 102 is Soon-Shiong, and it's basically the same problem again. Soon-Shiong also does not mention anything except encapsulating. Soon-Shiong is 32 specific examples, and in not a single one of those is there any mention of heparin.

So again, Soon-Shiong also doesn't disclose each and every element of the claimed invention arranged or combined in the same way as in the Appellant's claims.

The third rejection's somewhat different. This is a publication of Nomura. Nomura, et al. The aim in the Nomura study was to evaluate various anti-coagulants, including heparin, on portal vein pressure, on recipient survival, and graft survival, when unpurified islets are transplanted into the portal vein.

Now Nomura,et al., disclosed the systemic administration of heparin. There is no preincubation of the islets with heparin, as is set forth in Appellant's claims.

And the preincubation is what causes the heparin to be bound to the surface. Nomura states that the unpurified islets were transplanted into the portal vein over three minutes. Fifteen minutes after the start of injection of the islets, portal vein pressure was measured and heparin was then injected.

Even assuming that islets and heparin were both injected into the portal vein at the same time -- which isn't really logical, because there's no reason to inject islets twice -- there is no opportunity for the heparin to become fixed to the surface of the islets.

Administration of the heparin in connection with islet transplantation in the portal vein means that the heparin would have been or was instantaneously diluted by the blood volume.

There is no disclosure of the possibility of preincubating the islets with heparin so as to fix or irreversibly adsorb the heparin onto the islets, as in the present invention.

Therefore, Nomura also does not anticipate the claims.

The rejections under Section 102 don't meet the requirements of 102. And the Appellants ask that the rejections be reversed.

If you have any other questions, I'll try to do my best.

JUDGE GRIMES: No. I think we got your position.

MR. NEIMARK: Thank you very much.

JUDGE GRIMES: Thank you for coming.

MR. NEIMARK: I appreciate it.

(Whereupon, at 1:13 p.m., the proceedings were concluded.)

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